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4. Summary of Safety and Effectiveness Information

Company Name and Address: Gerard Medical, Inc.
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Company Telephone No.: (508) 248-1562

Company Contact Name: Richard Cayer, Jr.

Summary Date: May 8, 1996

Proprietary Name: TrimPort

Common or Usual Name: Implanted Vascular Access System

Classification Name: Implanted Subcutaneous IV Catheter

Class: Unclassified

Legally Marketed Substantially Equivalent Devices:

Ideas' Port. Manufactured by Ideas for Medicine Inc.

LifePort with PolyCath Catheter. Manufactured by Strato Medical Corp.

Device Description and Intended Usage:

The Gerard Medical, Inc. TrimPort Implantable Access System is precision engineered to provide repeated access to the vascular system for both parenteral delivery of fluids and the withdrawal of venous blood.

The implantable segments of the TrimPort System and comparable devices are the portal, the radiopaque catheter, and a locking catheter connector.

The small veins in one's arms and hands can become severely damaged when subjected to frequent needle punctures and/or irritating fluids. Usage of a TrimPort device, which is implanted beneath the skin, frees patients from the discomfort and potential damage to veins from repeated injections into them.

The TrimPort catheter is implanted into a large blood vessel so that fluids can be introduced or blood withdrawn without the necessity for repeated injections into the patient's vein.

Once the implanted TrimPort is ready for use, the physician or nurse will cleanse the skin at the implantation site and will pinpoint the device's location by simply feeling the unobtrusive but clear outline of its top rim. A needle specific to this purpose will be inserted gently through the skin into the portal of the TrimPort, where it will remain throughout the fluid delivery-withdrawal process.

Device Design, Testing, and Potential Adverse Occurrences:

We have reviewed a great quantity of information regarding our own and many competitive implantable vascular access systems. Based on our analysis, we feel that there are specific occurrences that would negatively affect the safety and effectiveness of these devices. The following is a list of these potential adverse occurrences and a summary of what we have done to minimize the risks.

1. Catheter Disconnection:
   We designed an excellent catheter locking mechanism that remains intact, even under extreme conditions.
   To ensure that the surgeon implanting our TrimPort assembles the locking device properly, we provide clear and complete instructions and diagrams in our "Instructions for Use".

2. System Leak:
   We precisely engineered our TrimPort vascular access systems so that they perform properly (Re: two-way flow, leak tight), even under extreme misuse conditions. To ensure this, we mandate that all new designs must be able to pass each of our standard usage and extreme misuse tests.
   To minimize the possibility of misuse, we instruct those who access the device to use syringes that are 10cc or larger. This helps to prevent the emission of damaging pressure into the system. Our recommendations to use 10cc or larger syringes and not to exceed 40 psi when using the system is stated several times in our "Instructions for Use". Note that this is also a standard warning in the competitive instruction manuals we have reviewed.

3. System Occlusions:
   We make numerous references, and provide much direction, in our "Instructions for Use" relative to flushing our device and clearing system occlusions.